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gene same (encod\$ or cod\$) same vaccine same liposome	125

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L2



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<u>L2</u>	gene same (encod\$ or cod\$) same vaccine same liposome	125	<u>L2</u>
<u>L1</u>	gene same (encod\$ or cod\$) same vaccine	4513	<u>L1</u>

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L2: Entry 63 of 125

File: USPT

Aug 13, 2002

DOCUMENT-IDENTIFIER: US 6432925 B1

TITLE: RNA cancer vaccine and methods for its use

Brief Summary Text (11):

DNA-based vaccination has shown to have a greater degree of control of antigen expression, toxicity and pathogenicity over live attenuated virus immunization. However, although in vivo DNA vaccination protocols are available, improvements in in vivo delivery and transgene expression are needed. For example, introduction of DNA into specific cells often results in degradation of the DNA by endosomes or lysosomes. Vaccines that require the tumor antigen to be expressed by tumor cells may result in problems such as suppression of immune responses or altered physiologic functions that modify antigen expression because tumor cells have many negative type regulating elements. Current approaches of in vivo delivery of DNA by retroviral or adenoviral vectors have problems related to efficacy, viral gene integration, potential pathogenic activity and immune response to viral vector encoding proteins. In addition, the DNA in DNA vaccines may be incorporated into the host cell's DNA, making it difficult to halt production of the tumor antigen when treatment is complete. Some liposome delivery systems are undesirable because they may incorporate into hemopoietic-derived cells such as lymphocytes.

Detailed Description Text (80):

REFERENCES Autran, B., et al., "Monoclonal B-cell Response to Diphtheria Toxoid: Evidence for Cross-Reactive Epitopes," Immunol. (1987); 60: 531-538. Cheung, I., and Cheung, N-K, "Molecular Detection of Gage Expression in Peripheral Blood and Bone Marrow: Utility as Tumor Marker for Neuroblastoma," Clin. Cancer Res., 3, 821-826 (1997). Conry, R. M., et al. "Characterization of a Messenger RNA Polynucleotide Vaccine Vector," Cancer Res. (1995); 55: 1397-1400. De Plaen, E. et al., "Structure, Chromosomal Localization, and Expression of 12 Genes of the MAGE Family," Immunogenetics (1994); 40: 360-369. Doi, F., Chi, D., Charuworn, B. B., Conrad, A., Russell, J., Morton, D. L., and Hoon, D. S. B., "Detection of B-human Chorionic Gonadotropin mRNA as a Marker for Cutaneous Malignant Melanoma," Int. J. Cancer, 65, 454-459 (1996). Dzau, V. J.; Mann, M. J.; Morishita, R.; Kaneda Y., "Fusigenic Viral Liposome for Gene Therapy in Cardiovascular Diseases," Proc. Nat'l Acad. Sci. USA (1996); 93: 11421-11425. Eynde, B., Peeters, O., Backer, O., Gaugler, B., Lucas, S., and Boon, T., "A New Family of Genes Coding for an Antigen Recognized by Autologous Cytolytic T Lymphocytes on a Human Melanoma," J. Exp. Med., 182, 689-698 (1995) Gerhard, M., Juhl, H., Kalthoff, H., Schreiber, H., Wagener, C., and Neumaier, M., "Specific Detection of Carcinoembryonic Antigen-expressing Tumor Cells in Bone Marrow Aspirates by Polymerase Chain Reaction," J. Olin. Oncol., 12, 725-729 (1994). Gomella, L. G. Raj, G. V., and Moreno, J. G., "Reverse Ttranscriptase Polymerase Chain Reaction for Prostate Specific Antigen in the Management of Prostate Cancer," J. Urology, 158, 326-337 (1997). Graham, R. A.; Burchell, J. M.; Beverly, P.; Taylor-Papadimitriou J., "Intramuscular Immunization with MUC1 cDNA Can Protect C37 Mice Challenged with MUC1-Expressing Syngeneic Mouse Tumor Cells," Int. J. Cancer (1996); 65: 664-670. Hoon, D. S. B., et al., "Detection of Occult Melanoma Cells in Blood with a Multiple-Marker Polymerase Chain Reaction Assay," J. Clin. Oncol. (1995); 13: 2109-2116. Hoon, D. S. B., Irie, R. F., "Current Status of Human melanoma Vaccines: Can They Control Malignant Melanoma? BioDrugs, 7, 66-84 (1997). Hoon, D. S. B., Irie, R. F., "Current Status of Melanoma Vaccines. Can They Control Malignant Melanoma?" BioDrug (1997); 1: 66-

84. Hoon, D. S. B., Sarantou, T., Doi, F., Chi, D., Kuo, C., Conrad, A., Schmid, P., Turner, R., and Guiliano, A., "Detection of Metastatic Breast Cancer by B-hCG Polymerase Chain Reaction," *Int. J. Cancer*, 69, 369-374 (1996). Hoon, D. S. B., Yuzuki D.; Hayashida M.; Morton, D. L., "Melanoma Patients Immunized with Melanoma Cell Vaccine Induce Antibody Responses to Recombinant MAGE-1 Antigen," *J. Immunol* (1995) 154: 730-737. Huygen, K., et al., "Immunogenicity and Protective Efficacy of a Tuberculosis DNA Vaccine," *Nature Med* (1996); 2: 893-898. Kaneda, Y., "Virus (Sendai Virus Envelope)-Mediated Gene Transfer," *Cell Biology: A Laboratory Handbook*, Academic Press, San Diego (1994), pp. 50-57. Kawakami, Y., Eliyau, S., Delgado, CH., et al., "Cloning of the Gene Coding for a Shared Human Melanoma Antigen Recognized by Autologous T cells Infiltrating into Tumour," *Proc. Natl. Acad. Sci., USA*, 91, 3515-3519 (1994). Kwon, S. K., "Pigmentation genes: The Tyrosinase Gene Family and the Pmel 17 Gene Family," *J. Invest. Dermatol.*, 100, 134S-140S, (1993). Mercer, E. H., et al., *Neuron* (1991); 7: 703-716. Michel, M. L., et al., "DNA-Mediated Immunization to the Hepatitis B Surface Antigen in Mice: Aspects of the Humoral Response Mimic Hepatitis B Viral Infection in Humans," *Proc. Nat'l Acad. Sci USA* (1995); 92: 5307-5311. Mivechi, N. F., and Rossi, J. J., "Use of Polymerase Chain Reaction to Detect the Expression of the Mr 70,000 Heat Shock Genes in Control or Heat Shock Leukemic Cells as Correlated to Their Heat Response," *Cancer Res.*, 50, 2877-2884 (1990). Nollau, P., Moser, C., Weinland, G., and Wagener, C., "Detection of K-Ras Mutations in Stools of Patients with Colorectal Cancer by Mutant-enriched PCR," *Int. J. Cancer*, 66, 332-336 (1996). Ralhan, R., and Kaur, J., "Differential Expression of Mr 70,000 Heat Shock Protein in Normal Premalignant, and Malignant Human Uterine Cervix," *Clin. Cancer Res.*, 1, 1217-1222 (1995). Saeki, Y., et al., *Hum. Gene Ther.* (1997); 8: 2133-2141. Sarantou, T., Chi, D., Garrison, D., Conrad, A., Schmid, P., Morton, D. L., and Hoon, D. S. B., "Melanoma-Associated Antigens as Messenger RNA Detection Markers for Melanoma," *Cancer Re.*, 57, 1371-1376 (1997). Sensi, M., Traversari, C., Radrizzani, M., Stefania, S., Maccalli, C., Mortarini, R., Rivoltini, L., Faina, C., Nicolini, G., Wlofel, T., Brichard, V., Boon, T., Bordignon, C., Anichini, A., and Parmiani, G., "Cytotoxic T-lymphocyte Clones from Different Patients display Limited T-cell-receptor Variable-region Gene Usage in HLA-A2 Restricted Recognition of the Melanoma Antigen Melan-A/ Mart 1," *Proc. Natl. Acad. Sci., USA*, 92, 5674-5678 (1995). Shirasawa, S., Furuse, M., Yokoyama, N., Sasazuki, T., "Altered Growth of Human Colon Cancer Cell lines Disrupted at Activated Ki-Ras," *Science*, 260, 85-88 (1993). Takahashi, T., Irie, R., Morton, D. L., and Hoon, D. S. B., "Recognition of gp43 Tumor-associated Antigen Peptide by Both HLA-A2 Restricted CTL Lines and Antibodies from Melanoma Patients," *Cell. Immunol.*, 178, 162-171 (1997). Vijayasaradhi, S., Bouchard, B., and Houghton, A. N. "The melanoma Antigen gp75 is the Human Homologue of the Mouse b (brown) Locus Gene Product," *J. Exp. Med.*, 171, 1375-1380 (1990). Wang, B., et al., "Gene Inoculation Generates Immune Responses Against Human Immunodeficiency Virus Type 1," *Proc. Nat'l Acad. Sci. USA* (1993); 90: 4156-4160. Wolf, J. A., et al., "Long-Term Persistence of Plasmid DNA and Foreign Gene Expression in Mouse Muscle," *Hum. Mol. Genet.* (1992); 1: 363-369. Wolfel, T., Van Pel A., Brichard V., et al., "Two Tyrosinase Nonapeptides Recognized on HLA-A2 melanoma by Autologous Cytolytic T lymphocytes," *Eur J. Immunol.*, 24, 759-764 (1994). Yanagihara, I., et al., "Expression of Full-Length Human Dystrophin cDNA in MDX Mouse Muscle by HVJ-Liposome Injections," *Gene Therapy* (1996); 3: 549-553. Yokoyama, K., Yasumoto, K., Suzuki, H., and Shibahara, S., "Cloning of the Human DOPAchrome Tautomerase/tyrosinase-related Protein 2 Gene Identification of Two Regulatory Regions Required for its Pigment Cell-specific Expression," *J. Biol. Chem.*, 269, 27080-27087 (1994). Yoshino, I., Goedegebuure, P., Peoples, G., Lee, K-Y., and Eberlein, T., "Human Tumor-infiltrating CD4+ T Cells React to B Cell Lines Expressing Heat Shock Protein 70," *J. Immunol.*, 153, 4149-4158 (1994). Zhang, Y., Zippe, C., Van Lente, F., Klein, J., and Gupta, M., "Combined Nested Reverse Transcription-per Assay for Prostate-specific Antigen and Prostate-specific Membrane Antigen in Detecting Circulating Prostatic Cells," *Clin. Cancer Res.*, 3, 1215-1220 (1997).

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L2: Entry 66 of 125

File: USPT

Jun 18, 2002

DOCUMENT-IDENTIFIER: US 6406705 B1

TITLE: Use of nucleic acids containing unmethylated CpG dinucleotide as an adjuvant

Detailed Description Text (85):

Other vectors include plasmid vectors. Plasmid vectors have been extensively described in the art and are well-known to those of skill in the art. See e.g., Sanbrook et al., "Molecular Cloning: A Laboratory Manual," Second Edition, Cold Spring Harbor Laboratory Press, 1989. In the last few years, plasmid vectors have been used as DNA vaccines for delivering antigen-encoding genes to cells in vivo. They are particularly advantageous for this because they do not have the same safety concerns as with many of the viral vectors. These plasmids, however, having a promoter compatible with the host cell, can express a peptide from a gene operatively encoded within the plasmid. Some commonly used plasmids include pBR322, pUC18, pUC19, pRC/CMV, SV40, and pBlueScript. Other plasmids are well-known to those of ordinary skill in the art. Additionally, plasmids may be custom designed using restriction enzymes and ligation reactions to remove and add specific fragments of DNA. Plasmids such as those used for DNA vaccines may be delivered by a variety of parenteral, mucosal and topical routes. For example the plasmid DNA can be injected by intramuscular, intradermal, subcutaneous or other routes. It may also be administered by intranasal sprays or drops, rectal suppository and orally. It may also be administered into the epidermis or a mucosal surface using a gene-gun. The plasmids may be given in an aqueous solution, dried onto gold particles or in association with another DNA delivery system including but not limited to liposomes, dendrimers, cochleate and microencapsulation.

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L2: Entry 71 of 125

File: USPT

Jan 15, 2002

DOCUMENT-IDENTIFIER: US 6339065 B1

TITLE: Episomal expression vector for human gene therapy

Detailed Description Text (67):

While any gene that can be expressed in a mammalian cell may be incorporated into a transfection vector as the foreign gene according to this invention, preferred genes will be those whose expression in a target cell population will counter-act a disease process. For example, an episomal gene therapy vector could be used to target the immune system to kill cancer cells in vivo. Tumor cell lines transfected with cytokine cDNA have been successfully used as cancer vaccines (Connor, et al., 1993, J. Exp. Med., 177:1127-1134; Golumbek, et al., 1991, Science, 254:713; Porgador, et al., 1992, Cancer Res., 52:3678; Aoki, et al., 1992, Proc. Natl. Acad. Sci. USA, 89:3850) and transfection of tumor cells in vivo with appropriate episomal vectors will enhance tumor kill, since episomal replication in the tumor cell will efficiently produce the desired high local concentration of cytokines, thereby stimulating immune effector cells. One such example is introduction of episomal expression vectors encoding interleukin-2 into bladder cancer cells in vivo via instillation of liposome/DNA complexes directly into the bladder lumen. Another example is transfection of lung cancer cells in vivo with interleukin-6 via inhalation of aerosolized liposome/DNA complexes (see Stribling, et al., 1992, Proc. Natl. Acad. Sci. USA, 89:11277-11281, for method using non-episomal vectors). Other gene therapy approaches to kill cancer cells include expression of genes conferring drug susceptibility, such as transfection with herpes simplex thymidine kinase encoding vectors followed by ganciclovir treatment. (Culver, et al., 1992, Science, 256:1550-1552 used integrating vectors. Replacing the integrating vector with an episomal expression vector will enhance the level of susceptibility conferring enzyme.) Other foreign gene sequences whose expression by a patient's cells would counter-act a disease process will be apparent to those skilled in the art.

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File: USPT

Sep 25, 2001

DOCUMENT-IDENTIFIER: US 6294378 B1

TITLE: Method and reagents for genetic immunization

Detailed Description Text (25):

The nucleic acid constructs containing the promoter, antigen-coding region and sorting region can be administered directly or they can be packaged in liposomes or coated onto colloidal gold particles prior to administration. Techniques for packaging DNA vaccines into liposomes are known in the art, for example from Murray, ed. "Gene Transfer and Expression Protocols" Humana Pres, Clifton, N.J. (1991). Similarly, techniques for coating naked DNA onto gold particles are taught in Yang, "Gene transfer into mammalian somatic cells in vivo", Crit. Rev. Biotech. 12: 335-356 (1992), and techniques for expression of proteins using viral vectors are found in Adolph, K. ed. "Viral Genome Methods" CRC Press, Florida (1996).

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